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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/514,928	02/28/2000	Peter J. Wilk	W07-428	9269

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EXAMINER

JAWORSKI, FRANCIS J

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/514,928

Applicant(s)

WILK ET AL.

Examiner

Jaworski Francis J.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-21, 31 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-36 and 39-42 is/are allowed.
- 6) ☒ Claim(s) 13-21, 43-45 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: IDS filed 9-4-03 missing from file.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 43-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a) producing a 3D representation or enhanced representation of internal organic structure, and b) eliminating the need for self-coherency by rigidification of the sensor carrier mount, does not reasonably provide enablement for a) producing an internal structure 'model' or b) maintaining sensors in fixed relation to a patient during data-gathering, both as called for in base claim 43.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

With respect to issue a) the specification teaches only a method for producing a three-dimensional ultrasound image representation of tissue, or an enhanced (outlined or colorized for example) such representation or a surface rendering (meaning overlay organ image portions removed) of such a representation. The term 'model' by contrast is not found in the specification of this or the parent cases and embraces other meanings such as stylizations and categorizations. By analogy a picture of an aircraft is distinct from and not synonymous with a model of an aircraft.

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With respect to issue b) the specification teaches only a method for accounting for positional locations of the transducers or sensors with respect to each other or fixing the position with respect to each other. Specifically, when the sensor carrier is made to be either as a flexible sheet or is made to be rigid but in sections or panels movable with respect to each other at flexion joints a self-coherency algorithm is invoked by which the sensors become referenced to each other via associated positional sensors. When on the other hand the carrier is rigid in toto such as in Figs. 17 or 18, self-coherency is stated to no longer be needed. Otherwise it is taught that reference scatterers may be used or a coherency algorithm used to organize the image representation. Fixing the carrier and sensor locations with respect to the patient and maintaining such fixation during data-gathering is by contrast never taught in the specification of this or the parent cases and the terms fix or fixed or maintain/sustain fix(ation) thus do not appear in the original disclosure of this application.. In fact, absent further teaching, the interposition in all cases of a flexible fluid coupling sac or 'waterbed' flexible sac support cannot serve as a rigid fixation to a patient and one may equally assume that the coherency algorithm or scatterer referencing is what serves as a basis to spatially organize image data without the constraint of sustained positional fixation of carrier(s) and sensor(s) to the patient.

Dependent claims 44-45 inherit these deficiencies.

Claim Rejections - 35 USC § 102

(Parenthesized claim numerals pertain to the claim or claims to which the immediately preceding argument is directed).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13 , 18, 20-21, 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Mochizuki et al (US5152294) which teaches a medical diagnostic ultrasound scanning method including providing a carrier including 28 and the housing of assembly 20 including attachment surface 28A for holding a plurality of ultrasound electromechanical (i.e. electrical input-to-pressure wave output) transducer elements 30a to the carrier, placing such a scanner in pressure wave transmitting contact with the patient's skin - see col. 1 lines 13-26, the generated ultrasonic pressure waves produced by transmitter 104 necessarily having 'at least one... frequency' to constitute a programmed transmit wave and propagate, receiving the echoes from the transducers at 106 and performing 3D volumetric data acquisitions via electronic scanning as per abstract and the operation of element 110, and display 112. Since all of the transducers contribute to the transmit and receive beams, any distinct subsets then constitute a first transmit plurality and second, receive plurality..(Claims 13, 20).

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Backing 18 (28) and the casing of 20 is necessarily at least partly rigid in order for structural integrity as shown; 52 defines an interposed fluid-filled intervening bag. Disposed against the patient in the Mochizuki et al method. (Claim 18).

The transducers as shown in Figs. 1 and 2 are mounted in fixed positions with respect to each other throughout the scanning procedure, and the avowed purpose of Mochizuki et al is to extend the fixed stationary contact relationship of linear array, two-dimensional scanning to three-dimensions by the provision of the housing 20 by which the linear array may be mechanically scanned in elevation while the carrier is fixedly disposed, see col. 1 line 52-col. 2 line 14 vs col. 2 lines 29-47.. (Claims 21, 43).

A three-dimensional 'model' meaning video echo intensity representation is then produced by the three-dimensional echo data alone, see col. 7 lines 20-48. (Claims 44-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mochizuki et al in view of Barthe et al (US6213948). Mochizuki et al uses of a convex array face hence the transmission beam is naturally steered outwardly along the azimuth. Whereas Mochizuki et al does not teach phased array use it would have been obvious in view of Barthe et al col. 3 lines 45-46 to use a phased array as a

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straightforward equivalent in this art since the time-delay phasing implicit in phased array use allows beam steering along the azimuth while presenting a flat emission face profile for contact with generally planar small skin surface regions of the patient.

Claims 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mochizuki et al in view of Barthe et al as applied to claim 14 above, and further in view of Matsushima et al. Barthe et al as noted above establishes that operating a phased array would have been a well-known equivalent to operating a convex array for purposes of obtaining a sector scan in a combined electronic and mechanical scanner as taught in Mochizuki et al , however neither reference provides further detail as to how delay phasing might be accomplished. It would have been obvious in view of Matsushima et al for example col. 6 lines 53-61 to provide switching matrices to selectively connect incremental delays to accomplish beam steering and focusing since this reduces the cost of delay element redundancies which would otherwise be necessarily without the flexible tap-in architecture provided by switching. (Claim 15).

Since the groupings of transducers in Matsushima et al change, see for example Fig. 11, the sampling times and phases and therefore switching times of the receive plurality active at any moment also varies. (Claim 16, 17). .

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mochizuki et al in view of Barthe et al, and further in view of Pittaro (US5113706). Mochizuki et al and Barthe et al are silent regarding details of array parameter adjustments such as delay/switching as noted supra. However it would have been obvious in view of Pittaro that, particularly when operating a focused or phased array

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one would wish to vary transmission frequency with range or depth zone as per col. 5 lines 7-22 since ultrasound attenuation with depth is frequency-dependent and therefore it is desirable to use lower frequency carrier bursts to ensonate deeper tissue layers.

Allowable Subject Matter

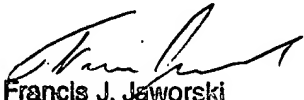
Claims 31 – 36 and 39-42 are allowed.

Li et al (IEEE Trans. FFC V42 #1 1/1995) and Steinberg et al (US4395909) col. 1 lines 32-45, col. 6 lines 8-24 and Hossack et al (US5680863) are all cited as of interest as relating to conforming arrays with flexible carrier backing. Miwa et al (US4434661) and Holmberg (US6135960) are cited as pertaining to segmented ultrasound array carriers.

This action is not made final however the case should be prepared for final action.

FJJ:fjj

4-28-04


Francis J. Jaworski
Primary Examiner